

# PDUFA II Fee and Revenue Estimation Worksheet

## FY 2000 Updated Estimate

Actual Amounts Collected as of 9/30/99 shown for FY 1998 and FY 1999

Forecast for 2000 through 2002 based Regression Analysis Trendline of Submissions from FY 1993 through FY 1999

Fiscal Year	1998 Actual <sup>3</sup>	1999 Actual <sup>3</sup>	2000 Estimate	2001 Estimate	2002 Estimate
Statutory Full Application Fee	\$250,704	\$256,338	\$256,338	\$267,606	\$258,451
Cumulative Inflation Percentage since 1997 <sup>1</sup>	2.45%	6.22%	11.47%	15.59%	19.87%
Fee per Full Application, after Inflation	\$256,846	\$272,282	\$285,740	\$309,330	\$309,802
Estimated Equivalent of Full Applications <sup>2</sup>	119	155	158	166	174
<b>Est. Total Application Fee Revenue</b> After Accounting for Waivers	\$30,493,387	\$42,327,064	\$45,146,983	\$51,348,848	\$53,905,489
<b>Est. Total Product Fee Revenue</b>	\$41,364,975	\$39,188,776	\$45,146,983	\$51,348,848	\$53,905,489
Estimated # of Products	2225	2134	2262	2262	2262
Product Fee	\$18,591	\$18,364	\$19,959	\$22,701	\$23,831
<b>Est. Total Establishment Fee Revenue</b>	\$45,439,914	\$40,490,948	\$45,146,983	\$51,348,848	\$53,905,489
Estimated # of Establishments	320	315	318	318	318
Establishment Fee	\$141,966	\$128,435	\$141,971	\$161,474	\$169,514
<b>Estimate of Total Revenue</b>	\$117,122,000 <sup>4</sup>	\$122,006,787	\$135,440,948	\$154,046,543 <sup>5</sup>	\$161,716,467
Five-Year Total:					<b>\$690,332,754</b>

<sup>1</sup>Based on increases of 2.45% in 1998, 3.68% in 1999, 4.94% in 2000, and estimated at 3.7% each year thereafter.

<sup>2</sup>Number after allowing for Exemptions and Waivers--FY 2000 through FY 2002 Estimates Based on Latest Trendline.

<sup>3</sup>Actual Figures are as of 9/30/1999 and will be adjusted by both accounts receivable collected and waivers granted.

<sup>4</sup>Actual Total for FY 1998 is \$117,298,275. The amount shown as the total is the amount appropriated from fees in FY 1998. Fees collected in excess of \$117,122,000 will be used to offset collections in a later year.

<sup>5</sup>The President's FY 2001 Budget estimates \$149 million, but data available after that budget was submitted indicate that about \$154 will be collected in FY 2001. A supplemental budget request supporting this larger amount is under discussion.